

CANNON BUILDING 861 SILVER LAKE BLVD., SUITE 203 DOVER, DELAWARE 19904-2467

STATE OF DELAWARE DEPARTMENT OF STATE DIVISION OF PROFESSIONAL REGULATION BOARD OF PHARMACY

TELEPHONE: (302) 744-4500 FAX: (302) 739-2711 WEBSITE: DPR.DELAWARE.GOV

APPLICATION FOR IN-STATE PHARMACY REMODELING PERMIT

Instruction Sheet

Requirements for All Remodeling Applications

| File this application when an in-state Pharmacy-Retail or Pharmacy-Hospital plans to remodel its facility. | | | | |
|--|--|--|--|--|
| | Submit completed, signed and notarized Application for In-State Remodeling Permit. | | | |
| | Enclose remodeling fee by check or money order made payable to "State of Delaware." | | | |
| | Enclose three sets (copies) of the plans for the remodeled pharmacy department. Plans must be drawn to scale and should include the location of the sink, all doors, storage room, approved Schedule II controlled substance safe, security systems, and counters. For specific requirements, refer to 24 <u>Del.C. §2533</u> and Section 3.0 of the Board's <u>Rules and Regulations</u>, both available at <u>www.dpr.delaware.gov</u>. Plans must also show the type of alarm system installed and the name, address, and phone of the provider. | | | |
| | Arrange for the pharmacist-in-charge to sign the PHARMACIST IN CHARGE ACKNOWLEDGMENT section. | | | |
| | Submit a sample patient profile that meets the requirements in Section 5.0 of the Board's Rules and Regulations, | | | |
| Re | quirements Related to Temporary Facility | | | |
| | he pharmacy will operate from a temporary location during the remodeling, what you need to do depends on where the nporary facility is. | | | |
| • | If the temporary facility <i>is in the same building and has the same mailing address as the permanent facility</i> undergoing remodeling, this remodeling application is also an application for a temporary permit for the temporary pharmacy. In this situation, it is not necessary to file a separate application for the temporary pharmacy. If the temporary facility <i>is in a different building or has a different mailing address than the permanent facility</i> undergoing remodeling, this remodeling application does <u>not</u> cover the temporary pharmacy. In this situation, you must file an <i>Application for In-State Pharmacy Permit</i> for the temporary pharmacy. | | | |
| | If the temporary pharmacy will be in the same building with the same mailing address , enclose three sets of plans for the temporary location with the remodeling application . Make clear which set of plans are for the remodeled location and which are for the temporary location. | | | |
| | If the temporary pharmacy will be in the <i>different building with different mailing address</i> , follow the <u>instructions for submitting the <i>Application for In-State Pharmacy Permit</i></u> available at www.dpr.delaware.gov. You may submit the <i>Application for In-State Pharmacy Permit</i> with the remodeling application or separately. If you submit them together, make clear which documents (e.g., plans) pertain to which application. If you submit them separately, make sure that each application references the other. | | | |

Inspection Requirement

The temporary facility, regardless of whether or not it is in the same building, must also be inspected before it begins operation. A pharmacy representative *must notify the Board office* when the temporary location is ready for inspection.

The Board will review and tentatively approve the remodeling application contingent on the pharmacy passing final inspection. A pharmacy representative *must notify the Board office* when the remodeled pharmacy is ready for inspection. When the pharmacy passes the final inspection, the Board office will transfer the prior license number to the remodeled pharmacy.



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LOCATION AND CONTACT INFORMATION – The questions in this section are about the pharmacy location that will be undergoing remodeling.

| 1. | Pharmacy Name: | | | | |
|-----|---|------------|-----------------|-----------------------|--|
| | Enter name as it appears on current license |). | | | |
| 2. | Delaware Pharmacy License Number: A | | | | |
| 3. | Name of Proprietor Company (if different): | | | | |
| 4. | Address of Pharmacy's Permanent Physical Location : | | | | |
| | Street (no PO Box) | | | | |
| | City | <u>DE</u> | | | |
| | City | State | Zip | | |
| 5. | Permanent Mailing Address of Pharmacy (if different): | | | | |
| | | | | | |
| | City | | State | Zip | |
| 6. | Contact Person Name: | | | | |
| 7. | Phone: Fax: | | | | |
| 8. | Email: | | | | |
| 9. | Federal (DEA) Controlled Substances Registration Number: | | | | |
| 10. | Delaware (CSA) Controlled Substance Registration Number: | | | | |
| 11. | Will the Pharmacy temporarily operate from another location durin If yes, continue to the INFORMATION ABOUT TEMPORARY PH If no, skip to the INFORMATION ABOUT REMODELED PHARMA | IARMACY | section. |] No [] | |
| bui | FORMATION ABOUT TEMPORARY PHARMACY – If a pharmacy ilding and have the same mailing address as the permanent location apporary quarters. The questions in this section are about the pharm | n, a tempo | orary license w | ill be issued for the | |
| 12. | Is the temporary location in the same building and at the same m undergoing remodeling (Questions 4 and 5 above)? Yes \(\subseteq \) No If yes, continue with the next question. If no, submit a new <i>Application for In-State Pharmacy</i> to apply | | · | | |

Skip to the INFORMATION ABOUT REMODELED PHARMACY section. (Since the temporary permit does

not apply, the rest of this section does not apply.)

| 13 | . How long do you anticipate the | pharmacy will be | e operating t | rom this ten | nporary location? _ | |
|----|--|---|--|--|--|-------------------------------|
| 14 | . Pharmacy Department hours: | Saturday Sunday | | AM to | PM PM | |
| 15 | . Enter Hours of Business Site: | Saturday Sunday | | AM to | PM PM | |
| 16 | . The Prescription Department multiple The prescription counter must be merchandise for each pharmacis inches wide and shall be kept frequirements be met at the temporary in the prescription of the prescrip | e at least 18 inch st working concu ee of obstructior | nes wide with irrently. The n at all times | n four linear aisle behin . (See 24 <i>E</i> | feet kept clear and d the counter must | free of all be at least 30 |
| 17 | 7. Will the temporary location have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices? Yes \(\sigma\) No \(\sigma\) | | | | | |
| 18 | 8. Will the temporary location have a dispensing area of adequate size and space for proper compounding, dispensing, and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel? Yes No | | | | | |
| 19 | The area in which drugs and devices are stored must be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit. Will the temporary location have sufficient environmental control, i.e. lighting, ventilation, heating, and cooling, to maintain the integrity of drugs and devices? Yes \(\square\) No \(\square | | | | | |
| 20 | The sink in the pharmacy area must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized. Will the temporary location's pharmacy area contain a sink with hot and cold running water? Yes \square No \square | | | | | |
| 21 | Refrigerators and freezers (where required) will be maintained at the USP/NF range: Refrigerator – 36 ° to 46 ° Fahrenheit; Freezer – minus 4 ° to plus 14 ° Fahrenheit. Will the temporary location have suitable refrigeration with appropriate monitoring device? Yes \square No \square | | | | | |
| 22 | An area must be provided to afford the patient privacy from auditory detection by any unauthorized person(s In most settings, an area partitioned by a 5 foot divider on 2 sides with a minimum of 9 square feet will satisfy this requirement. Will the temporary location have an area which assures patient privacy to facilitate counseling? Yes \(\Boxed{\text{No}}\) No \(\Boxed{\text{No}}\) | | | | | |
| 23 | . Do the floor plans for the temporaddress, and phone number of t | | | of alarm sy | stem installed and | the name, |
| 24 | . When a pharmacist is not physic department must be physically of must be not less than five fee his requirement? Yes \(\simega\) No \(\simega\) | or electronically s | secured form | floor to ceil | ing. The partitione | d off section |
| | Enclose three sets (copies) of | building plans | , drawn to | scale, for th | ne temporary phai | rmacy. |

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remodeled permanent location. 25. Pharmacy Department hours: Weekdays _____ A.M. to _____ PM Saturday _____ A.M. to _____ PM _____ A.M. to _____ PM Sunday _____ A.M. to _____ PM Holidays Weekdays Saturday _____ A.M. to _____ PM 26. Enter Hours of Business Site: _____ A.M. to _____ PM Sunday _____ A.M. to _____ PM Holidays A.M. to PM 27. The Prescription Department must occupy at least 250 square feet of floor space excluding a storeroom. The prescription counter must be at least 18 inches wide with four linear feet kept clear and free of all merchandise for each pharmacist working concurrently. The aisle behind the counter must be at least 30 inches wide and shall be kept free of obstruction at all times. (See 24 Del. C. §2533.) Will these requirements continue to be met at the remodeled pharmacy? Yes No 28. Will the remodeled pharmacy have sufficient size, space, sanitation, and environmental control for adequate distribution, dispensing, and storage of drugs and devices? Yes No 29. Will the remodeled pharmacy have a dispensing area of adequate size and space for proper compounding, dispensing, and storage of drugs and devices, to ensure the safety and well being of the public and pharmacy personnel? Yes No 30. The area in which drugs and devices are stored must be accurately monitored using control devices to maintain room temperature between 59° and 86° Fahrenheit. Will the remodeled pharmacy have sufficient environmental control, i.e. lighting, ventilation, heating, and cooling, to maintain the integrity of drugs and devices? Yes ☐ No ☐ 31. The sink in the pharmacy area must be large enough to accommodate the equipment required by the Board so that the utensils can be properly washed and sanitized. Will the remodeled pharmacy contain a sink with hot and cold running water? Yes No 32. Refrigerators and freezers (where required) will be maintained at the USP/NF range: Refrigerator – 36 ° to 46 ° Fahrenheit; Freezer – minus 4 ° to plus 14 ° Fahrenheit. Will the remodeled pharmacy have suitable refrigeration with appropriate monitoring device? Yes \(\square\) No \(\square\) 33. An area must be provided to afford the patient privacy from auditory detection by any unauthorized person(s. In most settings, an area partitioned by a 5 foot divider on 2 sides with a minimum of 9 square feet will satisfy this requirement. Will the remodeled pharmacy have an area which assures patient privacy to facilitate counseling? Yes No 34. Do the floor plans for the remodeled pharmacy include the type of alarm system installed and the name, address, and phone number of the provider? Yes \(\text{No} \) 35. When a pharmacist is not physically present but the operation is open for business, the pharmacy department must be physically or electronically secured form floor to ceiling. The partitioned off section must be not less than five fee high measured from the floor. Will the remodeled pharmacy meet this requirement? Yes \quad No \quad \quad Enclose three sets (copies) of building plans, drawn to scale, for the remodeled pharmacy department and a sample patient profile.

INFORMATION ABOUT REMODELED PHARMACY – The questions in this section are about the pharmacy's

PHARMACIST-IN-CHARGE ACKNOWLEDGMENT

| compliance with ap | plicable state and federal laws. | |
|--|---|---|
| Pharmacist-in-Cha | arge Signature: | Delaware License A1 - |
| <u>complete</u> applicat be considered at a | a Board meeting, pharmacy remodeling pe r to the next scheduled meeting. The sche | nentation and correct payment. In order to ermit applications must be submitted at |
| Applications that a discarded. | are not <u>complete</u> within six (6) months of f | filing may be considered abandoned and |
| | AFFIDAVIT | |
| | ffirm under penalty of perjury that all the foregon of my knowledge and belief. I hereby further a | |
| Signature: | | Date: |
| Print Name: | Position | n: |
| State: | County: | |
| Sworn or aff | firmed before me a Notary Public this | day of 2 |
| | Notary Public: | |
| SEAL | My commission expires on | |

I understand that I am responsible for conducting and managing the prescription department in

APPLICATIONS THAT ARE NOT SIGNED, NOT NOTARIZED, INCOMPLETE OR NOT ACCOMPANIED BY THE REQUIRED FEE WILL BE REJECTED.